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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,746	06/22/1999	GREGORY M. GLENN	PM-254811	9348

7590 03/22/2004

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/337,746

Applicant(s)

GLENN ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and remarks, filed 12/03/03, are acknowledged. In view of the amendment removing most of the limitations necessitating the previous rejections, only the following rejections remain.
2. New Claims 71-95 are pending and under examination.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. As previously applied to Claims 1-42, 53-57, 59-63, and 65-69, new Claims 71-72, 75-87, and 90-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

a method for transcutaneous immunization (TCI) comprising applying a formulation to hydrated skin,

does not reasonably provide enablement for,

A) a method for TCI comprising applying diphtheria toxin (DT),
B) a method for TCI wherein the induced immune response recognizes a lipopolysaccharide (LPS),
C) a method for TCI wherein the induced response recognizes influenza virus hemagglutinin (HA), influenza virus nucleoprotein (NP), Hemophilus influenza B polysaccharide conjugate (Hib-PS), and *Escherichia coli* colonization factor CS6,

for the reasons of record first set forth in the paper mailed 12/04/01 and maintained in the papers mailed 8/06/02 and 6/03/03.

Applicant's arguments, filed 12/03/03, have been fully considered but they are not persuasive. Applicant has not addressed the enablement rejections but has merely indicated that the subject matter of the claims is adequately described in the specification.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321c may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. As previously applied to Claims 1-42, 53-57, 59-63, and 65-69, new Claims 71-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 3-35, 50-77, and 79-111 of copending Application No. 09/266,803. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application recite a method of TCI comprising employing an ADP-ribosylating exotoxin to induce an immune response. The claims of the '803 application recite a method of inducing an immune response employing a generic ADP-ribosylating exotoxin (Claim 30-33) or specific ADP-ribosylating exotoxins (Claims 22-26). The methods are therefore not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 12/03/03, have been fully considered but they are not persuasive. Applicant indicates that the new claims should not be subject to this rejection, but no specifics are discussed.

7. The following are new grounds for rejection.

8. Claims 71-95 and are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a "a modified ADP-ribosylating exotoxin ... modified to be less toxic" (Claims 71 and 81),

B) the "ADP-ribosylating exotoxin ... tetanus toxin" (Claims 72 and 87),

C) "a formulation comprised of antigen and adjuvant" (Claim 81),

D) "heat killed rabies virus" (Claim 85).

Regarding A), support has been found for "modified to be catalytically inactivated" but not the broader "modified to be less toxic".

Regarding B), tetanus toxin is not disclosed for use in a generic method as claimed.

Regarding C), Applicant states that support can be found in original Claim 1 and in two examples. Original Claim 1, however, specifically excluded a formulation comprising a separate antigen and adjuvant. Regarding the examples, examples disclosing specific formulations administered to specific mouse strains cannot be considered sufficient written description to support generic methods. i.e., the examples disclosing the administration of specific formulations (e.g., CT and BSA) to BALB/c mice cannot support claims drawn to the generic administration of any formulation to any subject.

Regarding D), again, a specific example cannot support a generic claim, and regardless, the example discloses only "killed rabies virus" and not "heat killed rabies virus".

9. Claims 71-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2, 5, 6, 11, 19, and 32 of copending Application No. 10/633,626. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an adjuvant or an antigen and an adjuvant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 71-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2, 5, 6, 11, 19, and 32 of copending Application No. 10/701,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an adjuvant or an antigen and an adjuvant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 71-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 5, 12, 14, and 17 of copending Application No. 10/435,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an adjuvant or an antigen and an adjuvant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. No claim is allowed.

13. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from

the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

15. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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3/18/04
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